K033281

NOV 26 2003



# Premarket Notification 510(k) Summary
# As required by section 807.92
# Datex Ohmeda S/5 Network and Central (iCentral) '03 with L-NET03 Software

**GENERAL COMPANY INFORMATION as required by 807.92(a)(1)**

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

October 10, 2003

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex Ohmeda S/5 Network and Central (iCentral) '03 with L-NET03 Software

COMMON NAME:

Remote monitoring device

CLASSIFICATION NAME:

The following Class II classification appears applicable:

| | | |
|---|---|---|
| MSX | System, network and communication, physiological monitors | 870.2300 |

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5 Network and Central '03 is substantially equivalent in safety and effectiveness to the Datex-Ohmeda S/5 Network and Central '02 (510(k) number: K022507).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Datex-Ohmeda S/5 Network (also referred as D-O Network in the related documentation) is a system, which consists of networked devices (which have separate 510(k) clearance) and the actual networking hardware. The networked devices are Datex-Ohmeda products containing a network adapter for physical access to the D-O Network as well as software modules supporting network access. Examples of currently available networked devices are:

1. Datex-Ohmeda S/5 Anesthesia Monitor
2. Datex-Ohmeda S/5 Compact Anesthesia Monitor
3. Datex-Ohmeda S/5 Critical Care Monitor
4. Datex-Ohmeda S/5 Compact Critical Care Monitor
5. Datex-Ohmeda S/5 Light Monitor
6. Datex-Ohmeda S/5 Cardiocap 5 Monitor
7. Datex-Ohmeda S/5 WebViewer
8. Datex-Ohmeda S/5 Network and Central, included in this 510(k)

The DeioRecorder for Anesthesia (formerly named as Datex-Ohmeda AS/3 Record Keeper) is also related to the D-O Network as an application using the services provided by the D-O Network.
No changes must be made to the Datex-Ohmeda S/5 Network and Central itself due to a new type of networked device. As a consequence, adding new types of Datex-Ohmeda devices to Datex-Ohmeda Network does not in any way affect the safety and effectiveness of Datex-Ohmeda Network or Central, if the devices are using the same protocol and the same design principles are followed as in the currently networked Datex-Ohmeda devices. The Datex-Ohmeda S/5 iCentral (also referred to as D-O iCentral in the related documentation) is the primary maintainer of communication between other networked devices and is, thus, an essential part of the network. The structure and functionality of the revised network corresponds to the structure and functionality of the substantially equivalent predicate device Datex-Ohmeda Network and Central '02 (510(k) number: K022507). The Datex-Ohmeda Network will be used for real-time communication between devices, for record keeping and for data management in a hospital. Practical examples of currently available features are:

- Transmission and display of measured values and alarms in the Datex-Ohmeda S/5 iCentral screen (central monitoring) and on the screen of another networked monitor (monitor-to-monitor communication).
- Anesthesia record keeping.
- Storing and transferring of trend and record keeping data in the network. When the patient is moved from one monitor to another, the data can be transferred with the patient. This feature includes also transferring data from/to an external system (HIS, laboratory, etc.) to/from Datex-Ohmeda S/5 Network.
- Printing of anesthesia records, ICU reports, trend printouts, spirometry loop printouts, waveform snapshot printouts, etc.

The actual networking hardware consists of cabling, patch panels, racks, connectors, repeaters, access points with antennas etc. The networking hardware is similar to the networking hardware of the substantially equivalent predicate device Datex-Ohmeda Network and Central '02 (510(k) number: K022507).

INTENDED USE as required by 807.92(a)(5)

Intended use:
The Datex-Ohmeda S/5 Network and Central is intended to be used with Datex-Ohmeda devices for displaying, storing, printing and otherwise processing information received from other networked devices.

Indication for use:
The Datex-Ohmeda S/5TM Network and Central transfers information between networked Datex-Ohmeda devices in the Datex-Ohmeda monitor network. It also allows information transfer between several iCentrals. Within one Datex-Ohmeda monitor network it allows a networked device to display, store, print and otherwise process information received from other networked devices.
The Datex-Ohmeda S/5TM iCentral maintains the network connections between the Datex-Ohmeda bedside monitors and other networked devices in Datex-Ohmeda monitor network. Network connections consist of hardwired network cables and/or Wireless LAN (WLAN) connections. Furthermore, it coordinates the transfer of information between devices in the Datex-Ohmeda S/5TM Network as well as between the Datex-Ohmeda Network and Hospital Information Systems (HIS).
The Datex-Ohmeda S/5TM iCentral can be used for remote monitor management, storing, printing, viewing, reviewing or otherwise processing of information from several bedside monitors or other networked devices.
The Datex-Ohmeda S/5TM Network will be used for patients in the hospital and it is meant for continuous use.
The device is for use by qualified personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5 Network and Central '03 is substantially equivalent in safety and effectiveness to the Datex-Ohmeda S/5 Network and Central '02 (510(k) number: K022507) currently in distribution

Similarities:
The indications for use are the same as in the predicate except that "reviewing" has been expressed in the statement and the S/5 ViewStation has been removed.
The structure and functionality of the Datex-Ohmeda S/5 Network and Central '03 closely corresponds to the structure and functionality of the Datex-Ohmeda Network and Central '02 (predicate). The basic architecture of Datex- Ohmeda S/5 Network and Central '03 is the same as that of Datex-Ohmeda Network and Central '02 (predicate).
The user interface, although an entirely new one, uses the same basic functionality as with the predicate: multiple patient views with the possibility to select a single patient for more detailed examination. Most alarm functionalities in the new S/5 iCentral and the predicate are identical.

Differences:
The user interface has been redone and it's now written using Microsoft Windows UI services. Several enhancements have been implemented to the UI e.g. multiple organ-specific single patient views are now offered. Also new parameters such as 12-lead ECG with ST values, EEG, NMT, Entropy, VO2/kg and VO2/m2 have been made available on the iCentral.
Full Disclosure and Event History for all patients has been added with the respective UI parts. Also the trend display has been improved although it still uses the methods proven in the predicate device.
Alarm management has been improved by introducing monitor groups so that multiple sets of monitors with separate alarm settings can now be defined. Also, if a monitor disconnects abnormally from the network a yellow alarm is produced in S/5 iCentral instead of the disconnection notification used in the predicate.
New printouts with the possibility to store the printout as a PDF file has been added. These new printouts are Admission information, 12-lead ECG, graphical and numerical trends and full disclosure.
The licensing has been altered to be software based instead of the predicate hardware based scenario. This has also enabled D-O to start licensing software features and not only the amount of monitors that are allowed to connect to a central station. The offered licenses that can be purchaced to activate features in the software are Trends and Alarm Management, Event History as well as Full Disclosure for either 28 or 72hrs.
Browser activation has been made available to allow users to access e.g. hospital Intranet right from the central station. Also viewing the generated PDF printouts is implemented utilizing the browser.

Summary:
In summary, the new Datex-Ohmeda S/5 Network and Central, described in this submission is substantially equivalent to the predicate device (K022507).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

Datex Ohmeda S/5 Network and Central (iCentral) '03 with L-NET03 Software complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested through validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- EN60950: 2000 (IEC60950 3rd edition) – Product Safety
- EN 55022: 1998 (IEC-CISPR 22) – Radio Frequency Interface
- EN 55024: 1998 – IT Equipment –Immunity characteristics
- EMC Directive 89/336/EEC (including amendments)
- Low Voltage Directive 73/23/EEC(amended by 93/68/EEC)
- EN 1441, Medical devices – Risk analysis
- EN 475, Medical devices - Electrically-generated alarm signals
- ISO 9703-1, ISO 9703-2, Anesthesia and respiratory care alarm signals
- IEC 60601-1-4 Medical electrical equipment. Part 1: General requirements for safety 4. Collateral Standard: Safety requirements for programmable medical systems.
- CAN/CSA-C22.2 No 950: Information Technology Equipment Including Electrical Business Equipment
- UL1950: Information Technology Equipment Including Electrical Business Equipment
- FDA/ODE Guidance for the Content of Premarket Submission for Software Contained in Medical Devices, May 29,1998
- FDA/ODE Guidance for the Off-The-Shelf Software Use in Medical Devices, September 9, 1999
- ISO/IEC 8802-3 (ANSI/IEEE 802.3),EIA/TIA-568, EIA/TIA-TSB40,international network cabling standards
- ETS 300 826 (1997-11) – Radio Wideband Systems

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Datex Ohmeda S/5 Network and Central (iCentral) '03 with L-NET03 Software as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 26 2003

Datex Ohmeda
c/o Mr. Joel C. Kent
Manager, Quality & Regulatory Affairs
86 Pilgrim Road
Needham, MA 02492

Re: K033281
Trade Name: Datex-Ohmeda S/5 Network and iCentral '03
Regulation Number: 21 CFR 870.2300
Regulation Name: System, Network & Communication, Physiological Monitors
Regulatory Class: Class II (two)
Product Code: MSX
Dated: October 10, 2003
Received: October 14, 2003

Dear Mr. Kent:

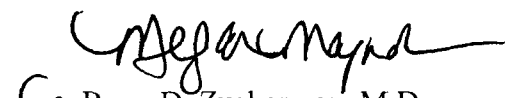
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033281



510(k) Number (if known): _____

Device Name: Datex-Ohmeda S/5 Network and iCentral '03

Indications For Use:

The Datex-Ohmeda S/5™ Network and iCentral transfers information between networked Datex-Ohmeda devices in the Datex-Ohmeda monitor network. It also allows information transfer between several iCentrals. Within one Datex-Ohmeda monitor network it allows a networked device to display, store, print and otherwise process information received from other networked devices.

The Datex-Ohmeda S/5™ iCentral maintains the network connections between the Datex-Ohmeda bedside monitors and other networked devices in Datex-Ohmeda monitor network. Network connections consist of hardwired network cables and/or Wireless LAN (WLAN) connections. Furthermore, it coordinates the transfer of information between devices in the Datex-Ohmeda S/5™ Network as well as between the Datex-Ohmeda Network and Hospital Information Systems (HIS).

The Datex-Ohmeda S/5™ iCentral can be used for remote monitor management, storing, printing, viewing, reviewing or otherwise processing of information from several bedside monitors or other networked devices.

The Datex-Ohmeda S/5™ Network will be used for patients in the hospital and it is meant for continuous use.

The device is for use by qualified personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033281